

§515.31

of the information the applicant is prepared to prove in support of his opposition to the Commissioner's proposal. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires a hearing. When it clearly appears from the information in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the refusal to approve the application or the revocation of approval of the application, the Commissioner will enter an order on this information, stating his/her findings and conclusions. If a hearing is requested and is justified by the applicant's response to the notice of opportunity for a hearing, the issues will be defined, an Administrative Law Judge will be named, and the Judge shall issue a written notice of the time and place at which the hearing will commence. In the case of denial of approval, such time shall be not more than 90 days after the expiration of such 30 days unless the Administrative Law Judge and the applicant otherwise agree; and, in the case of withdrawal of approval, such time shall be as soon as practicable.

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in the appearance.

§515.31 Procedures for hearings.

Hearings relating to new animal drugs under section 512(m)(3) and (m)(4) of the Federal Food, Drug, and Cosmetic Act (the act) shall be governed by part 12 of this chapter.

Subpart D—Judicial Review

§515.40 Judicial review.

The transcript and record shall be certified by the Commissioner of Food and Drugs (the Commissioner). In any case in which the Commissioner enters an order without a hearing under

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§314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

- Sec.
- 520.23 Acepromazine maleate tablets.
 - 520.44 Acetazolamide sodium soluble powder.
 - 520.45 Albendazole oral dosage forms.
 - 520.45a Albendazole suspension.
 - 520.45b Albendazole paste.
 - 520.48 Altrenogest solution.
 - 520.62 Aminopentamide hydrogen sulphate tablets.
 - 520.82 Aminopropazine fumarate oral dosage forms.
 - 520.82a Aminopropazine fumarate tablets.
 - 520.82b Aminopropazine fumarate, neomycin sulfate tablets.
 - 520.88 Amoxicillin oral dosage forms.
 - 520.88a Amoxicillin trihydrate film-coated tablets.
 - 520.88b Amoxicillin trihydrate for oral suspension.
 - 520.88c Amoxicillin trihydrate oral suspension.
 - 520.88d Amoxicillin trihydrate soluble powder.
 - 520.88e Amoxicillin trihydrate boluses.
 - 520.88f Amoxicillin trihydrate tablets.
 - 520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.
 - 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.
 - 520.90 Ampicillin oral dosage forms.
 - 520.90a Ampicillin capsules.
 - 520.90b Ampicillin trihydrate tablets.
 - 520.90c Ampicillin trihydrate capsules.
 - 520.90d Ampicillin trihydrate for oral suspension.
 - 520.90e Ampicillin trihydrate soluble powder.
 - 520.90f Ampicillin trihydrate boluses.
 - 520.100 Amprolium oral dosage forms.
 - 520.100a Amprolium drinking water.
 - 520.100b Amprolium drench.
 - 520.100c Amprolium crumbles.
 - 520.110 Apramycin sulfate soluble powder.
 - 520.154 Bacitracin oral dosage forms.
 - 520.154a Soluble bacitracin methylene disalicylate.
 - 520.154b Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder.
 - 520.154c Bacitracin zinc soluble powder.
 - 520.182 Bicyclohexylammonium fumagillin.
 - 520.222 Bunamidine hydrochloride.